

EXHIBIT 3

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Please note that the OMB number and expiration date may not have been determined when this Information Collection Request and associated Information Collection forms were submitted to OMB. The approved OMB number and expiration date may be found by clicking on the Notice of Action link below.

View ICR - OIRA Conclusion

OMB Control No: 1117-0056

ICR Reference No: 202012-1117-001

Status: Historical Inactive

Previous ICR Reference No:

Agency/Subagency: DOJ/DEA

Agency Tracking No:

Title: Reporting and Recordkeeping Requirements Related to Suspicious Orders

Common Form ICR: No

Type of Information Collection: New collection (Request for a new OMB Control Number)

Conclusion Date: 03/29/2021

Type of Review Request: Regular

Date Received in OIRA: 12/08/2020

OIRA Conclusion Action: Comment filed on proposed rule

Retrieve Notice of Action (NOA)

Terms of Clearance: OMB files this comment in accordance with 5 CFR 1320.11(c). This OMB action is not an approval to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995. This action has no effect on any current approvals. If OMB has assigned this ICR a new OMB Control Number, the OMB Control Number will not appear in the active inventory. For future submissions of this information collection, reference the OMB Control Number provided. OMB files this comment in accordance with 5 CFR 1320.11(c). This OMB action is not an approval to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995. This action has no effect on any current approvals. If OMB has assigned this ICR a new OMB Control Number, the OMB Control Number will not appear in the active inventory. For future submissions of this information collection, reference the OMB Control Number provided. In accordance with 5 CFR 1320, OMB is withholding approval of this information collection. Prior to the publication of the final rule, the agency must provide to OMB a summary of all comments pertaining to the information collection burden imposed by this rule and any changes made in response to these comments.

Inventory as of this Action	Requested	Previously Approved
Expiration Date	36 Months From Approved	
Responses	0	0
Time Burden (Hours)	0	0
Cost Burden (Dollars)	0	0

Abstract: This new information collection is related to the reporting of orders received under suspicious circumstances (ORUSCs). DEA implements and enforces titles I and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970), as amended (collectively, the CSA). 21 U.S.C. 801-971. The CSA requires registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances, i.e., orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency. Registrants are also required to "inform the Field Division Office of the Administration in the area of suspicious orders when discovered by the registrant." The collection would include two distinct components: the reporting of suspicious orders, and recordkeeping related to suspicious orders and ORUSCs. The collection would be applicable to registrants that distribute controlled substances, including manufacturers, distributors, importers, and pharmacies (and other practitioners in certain cases). Registrants would be required to file suspicious order reports through DEA's centralized database. Each report must contain: the DEA registration number of the registrant placing the order for controlled substances; the date the order was received; the DEA registration number of the registrant making the report; the National Drug Code number, unit, dosage strength, and quantity of the controlled substances ordered; the order form number for schedule I and schedule II controlled substances; the unique transaction identification number for the suspicious order; and what information and circumstances rendered the order actually suspicious.

Authorizing Statute(s): US Code: [21 USC 801-971](#) Name of Law: The Controlled Substances Act

PL: [Pub.L. 115 - 271 3291, 3292](#) Name of Law: The Preventing Drug Diversion Act of 2018

Citations for New Statutory Requirements: PL: Pub.L. 115 - 271 3291-3292 Name of Law: The Preventing Drug Diversion Act of 2018

Associated Rulemaking Information

RIN: 1117-AB47	Stage of Rulemaking: Proposed rulemaking	Federal Register Citation: 85 FR 69282	Date: 11/02/2020
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Federal Register Notices & Comments

Did the Agency receive public comments on this ICR? No

Number of Information Collection (IC) in this ICR: 1

IC Title	Form No.	Form Name
Reporting and Recordkeeping Requirements Related to Suspicious Orders	Not Applicable	Suspicious Orders of Controlled Substances Database

Burden increases because of Program Change due to Agency Discretion: Yes

Burden Increase Due to: Changing Regulations

Burden decreases because of Program Change due to Agency Discretion: No

Burden Reduction Due to:

Short Statement: This is a new information collection. Therefore there is not a previous burden to compare it to.

Annual Cost to Federal Government:

Does this IC contain surveys, censuses, or employ statistical methods? No

Does this ICR request any personally identifiable information (see [OMB Circular No. A-130](#) for an explanation of this term)? Please consult with your agency's privacy program when making this determination. Yes

Does this ICR include a form that requires a Privacy Act Statement (see [5 U.S.C. §552a\(e\)\(3\)](#))? Please consult with your agency's privacy program when making this determination. Yes

Is this ICR rela

Display additional information by clicking on the following: All Brief and OIRA conclusion

Is this ICR rela

Abstract/Justification Legal Statutes Rulmaking FR Notices/Comments IC List Burden Misc.

Is this ICR rela

Common Form Info. Certification

[View Information Collection \(IC\) List](#)

[View Supporting Statement and Other Documents](#)

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Common Form ICR: No

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous language that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8 (b)(3) about:
 - (i) Why the information is being collected;
 - (ii) Use of information;
 - (iii) Burden estimate;
 - (iv) Nature of response (voluntary, required for a benefit, or mandatory);
 - (v) Nature and extent of confidentiality; and
 - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected.
- (i) It uses effective and efficient statistical survey methodology (if applicable); and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item by leaving the box unchecked and explain the reason in the Supporting Statement.

Certification Date: 12/08/2020



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